

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Douglas G. Storey et al.

Application No.: 10/828,557

Filed: April 21, 2004

For: METHODS TO REGULATE

**BIOFILM FORMATION** 

Group Art Unit: 1645

**Examiner: ROBERT A ZEMAN** 

Confirmation No.: 5430

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By: A Cabello

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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Transmitted herewith for filing are the following:

- 1. Miscellaneous Communication;
- 2. Copy of previously presented Form PTO-1449;
- 3. Copies of two cited references; and
- 3. Return Receipt Postcard.

No fee is believed to be due in connection with the attached paper. However, in the event a fee is required please charge, or to credit any overpayment to, Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BUCHANAN INGERSOLL LLP

Date: April 26, 2006

sy: \_\_\_\_

Susan B. Fuller

Registration No. 51,979

P.O. Box 1404 Alexandria, VA 22313-1404 Tel: (858) 509-7300





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Kim A. Cabello

## **MISCELLANEOUS COMMUNICATION**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Please find attached copies of references cited in Applicant's previously submitted Form 1449. Although previously cited, the Examiner was unable to locate copies of the references. Applicants respectfully request that the Examiner consider the references attached and provide an initialed copy of the Form 1449 to Applicants accordingly.

Respectfully submitted,

**BUCHANAN INGERSOLL PC** 

Date: April 26, 2006

By: \_\_\_\_

Susan B. Fuller

Registration No. 51,979

P.O. Box 1404 Alexandria, Virginia 22313-1404 (858) 509-7300

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	NON-PATENT LITERATURE DOCUMENTS
Examiner · Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
RZ	Aarons, S. et al., "A regulatory RNA (PrrB RNA) modulates expression of secondary metabolite genes in Pseudomonas fluorescens F113," Journal of Bacteriology, 182(14):3913-3919 (2000).
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ρł	Barta et al., "Regulation of tabtoxin production by the lemA gene in <i>Pseudomonas syringae</i> ," J. Bacteriol. 174:3021-3029 (1992)
ft	Blumer, D., et al., "Multicopy suppression of a gacA mutation by the infC operon in Pseudomonas fluorescens CHA0: competition with the global translational regulator RsmA, FEMS Microbiology Letters, 187:53-58 (2000).
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ρt	Brinkman, F. et al., "Evolutionary relationships among virulence-associated histidine kinases, Infection and Immunity," 69:5207-5211 (2001).
RZ	Bullock, W.O. et al., "E. coli XL-Blue: a high efficiency plasmid transforming recA Escherichia coli strain with beta-galactosidase selection," Biotechniques, 5:376-378 (1987).
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xaminer	11 1 Date 9/7/65

Signature Considered 2/7/65

"EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

Substitute for form 14	estitute for form 1449A/PTO & 1449B/PTO			Complete if Known		
		IRS	T	Application Number	10/828,557	
·INFO	RMATIC	DNC	ISCLOSURE .	Filing Date	April 21, 2004	
			APPLICANT	First Named Inventor	Douglas G. Storey et al.	
	luse as man	v sheets	as necessary)	Examiner Name	ROBERT A ZEMAN	
Sheet	2	of	7	Attorney Docket Number	028722-381	

	NON-PATENT LITERATURE DOCUMENTS
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
fz	Corbell, N. et al. "A global regulator of secondary metabolite production in Pseudomonas fluorescens Pf-5," J. Bacteriol. 177, 6230-6236 (1995)
RZ	Costerton et al, "Microbial biofilms," Annu. Rev. Microbiol., 49:711-745 (1995)
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P7	Deziel, E. et al., "Initiation of biofilm formation by Psedomonas aeruginosa 57RP correlates with emergence of hyperpiliated and highly adherent phenotypic variants deficient in swimming, swarming, and twitching motilities," Journal of Bacteriology, 183:1195-1204 (2001).
PZ	Drenkard, E. et al., "Pseudomonas biofilm formation and antibiotic resistance are linked to phenotypic variation," Nature, 416:740-743 (2002).
RZ	Duffy, B. et al., "Controlling instability in gacS-gacA regulatory genes during inoculant production of Pseudomonas fluorescens biocontrol strains," Applied and Environmental Microbiology, 66:3142-3150 (2000).
· BF	Dybvig, K. et al., "DNA rearrangements and phenotypic switching in prokaryotes," Molecular Microbiology, 10:465-471 (1993).
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P2	Gault, M.H. et al. "Staphylococcal epidermidis infection of a hemodialysis button-graft complex controlled by vancomycin for 11 months," Nephron, 45:126-128 (1987).
PZ	Gomez-gomez, J. et al., "H-NS and RpoS regulate emergence of Lac Ara mutants of Escherichia coli MCS2," Journal of Bacteriology, 179(14):4620-4622 (1997).
βŧ	Grewal et al., "Identification and characterization of a locus which regulates multiple functions in Pseudomonas tolaasii, the case of brown blotch disease of Agaricus bisporus," J. Bacteriol., 177:4658-4668 (1995)
27	Han, B. et al., "Spontaneous duplication of a 661 bp element within a two-component sensor regulator gene causes phenotypic switching in colonies of Pseudomonas tolaasii, cause of brown blotch disease of mushrooms," Molecular Microbiology, 25:211-218 (1997).
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PZ	Heeb, S. et al., "Regulatory roles of the GasS/GasA two-component system in plant-associated and other gram-negative bacteria," Molecular Plant-Microbe Interactions, 14:1351-1363 (2001).
RE	Henderson, I. et al., "Molecular switches – the ON and OFF of bacterial phase variation," Molecular Microbiology, 33:919-932 (1999).
PZ	Heydorn, A. et al., "Statistical analysis of Pseudomonas aeruginosa biofilm development: impact of mutations in genes involved in twitching motility, cell-to-cell signaling, and stationary-phase sigma factor expression," Applied and Environmental Microbiology, 68(4):2008-2017 (2002).
· RZ	Hirano et al., "Role of Hrp type III secretion system in growth of Pseudomonas syringae pv. Syringae B728a on host plants in the field," Proc. Natl. Acad. Sci. USA, 96:9851-9856 (1999)
RE	Hoang, T. et al., "A broad-host-range Flp-Frt recombination system for site-specific excision of chromosomally-located DNA sequences: applications for isolation of unmarked Pseudomonas aeruginosa mutants," Gene, 212:77-86 (1998).

Examiner Signature Date Considered 9/7/05
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Substitute for form 144	9APTO & 14	49B/PTO		Соп	nplete if Known
	8	FIRS	T	Application Number	10/828,557
INFO	RMATI	ON D	ISCLOSURE	Filing Date	April 21, 2004
STATEMENT BY APPLICANT				First Named Inventor	Douglas G. Storey et al.
	fuse as man	v sheets a	as necessary)	Examiner Name	ROBERT A ZEMAN
Sheet	3	of	7 .	Attorney Docket Number	028722-381

	NON-PATENT LITERATURE DOCUMENTS
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
ft	Holloway et al., "Chromosomal genetics of Pseudomonas," Microbiol. Rev. 43:73-102 (1979)
27	Horii, T. et al., "Relationship between morphological changes and endotoxin release induced by carbapenems in Pseudomonas aeruginosa," Journal of Medical Mibrobiology, 48:309-315 (1999).
RZ	Hrabak et al., "The lemA gene required for pathogenicity of Pseudomonas syringae pv. Syringae on bean is a member of a family of two-component regulators," J. Bacteriol. 174:3011-3020 (1992)
βZ	Jander et al., "Positive correlation between virulence of <i>Pseudomonas aeruginosa</i> mutants in mice and insects. J. Bacteriol. 182:3843-3845 (2000)
PZ	Jensen et al., "Human polymorphonuclear leukocyte response to <i>Pseudomonas aeruginosa</i> grown in biofilms," Infect. Immun. 58:2383-2385 (1990)
RŁ	Jensen et al., "Complement activation by <i>Pseudomonas aeruginosa</i> biofolms," Microbiol. Path., 15:377-388 (1993)
fz	Jenson et al., "Some bacterial parameters influencing the neutrophil oxidative burst response to Pseudomonas aeruginosa biofilms," APMIS, 100:727-733 (1992)
RZ	Johnston et al., "Transcriptional activation of Salmonella typhimurium Invasion genes by a member of the phosphorylated response-regulator superfamily," Mol. Microbiol. 22:715-27 (1996)
· RZ	Kim, Y.C. et al., "Identification of adjacent genes encoding the major catalase and a bacterioferritin from the plant-beneficial bacterium Pseudomonas putida," Gene, 199:219-224 (1997)
. 82	Kim et al. "Sensor kinase GacS regulates production of quorum sensing factors, secondary metabolites and
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el	Kitten, T. et al., "Suppression of a sensor kinase-dependent phenotype in Pseudomonas syringae by ribosomal proteins L35 and L20," Journal of Bacteriology, 178:1548-1555 (1996).
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p:2	Koch, B. et al., "Lipopeptide production in Pseudomonas sp. Strain DSS73 is regulated by components of sugar beet seed exudate via the Gac two-component regulatory system," Applied and Environmental Microbiology, 68(9):4509-4516 (2002).
Rt	Kohler et al., "Swarming of <i>Pseudomonas aeruginosa</i> is dependent on cell-to-cell signaling and requires flagella and pili," J. Bacteriol. 182:5990-5996 (2000)
H	Kropp et al., "Increased emergence fo spring wheat after inoculation with Pseduomonas chlororaphis isolate 2E3 under field and laboratory conditions," Biol. Fertil. Soils, 23:200-206 (1996)
RZ	Lam et al., "Production of mucoid microcolonies by Pseudomonas aeruginosa within infected lungs in cystic
. P2	Liao et al., "Molecular characterization of two gene loci required for production of the key pathogenicity factor for pectate lyase in <i>Pseudomonas viridiflava</i> ," Mol. Plant – Microbe Interact. 7:391–400 (1994)
. Pt	Liao et al., "The repB gene required for production of extracellular enzymes and fluorescent siderophores in Pseudomonas viridiflava is an analog of the gacA gene in Pseudomonas syringae," Can. J. Microbiol. 42:177-182 (1996)
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lł	Mahajan-Miklos et al., "Molecular mechanisms of bacterial virulence elucidated using a <i>Pseudomonas</i> aeruginosa – Caenorhabditis elegans pathogenesis model," Cell, 96:47-56 (1999)

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stitule for form 144	9A/PTO & 14	9B/PTO		Сот	plete if Known
	9	IRS	7	Application Number	10/828,557
INFORMATION DISCLOSURE				Filing Date	April 21, 2004
STATEMENT BY APPLICANT				First Named Inventor	Douglas G. Storey et al.
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Rr	Marrie, T.J., "A scanning electron microscopic study of urine droppers and urine collecting systems,"  Archives of Internal Medinice, 143:1135-1141 (1983).
PE	Marrie, T.J. et al., "Scanning and transmission electron microscopy of in situ bacterial colonization of intravenous and intraarterial catheters," Journal of Clinical Microbiology, 19:687-693 (1984).
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fł	Meluleni et al., "Mucoid Pseudomonas aeruginosa growing in a blofilm in vitro are killed by opsonic antibodies to the mucoid exopolysaccharide capsule but not antibodies produced during chronic lung infection in cystic fibrosis patients," J. Immunol., 155:2029-2038 (1995)
ft	McClean et al., "Quorum sensing and Chromobacterium violaceum: exploitation of violacein production and and inhibition for the detection of N-acyl homoserine lactones," Microbiol., 143:3703-3711 (1997)
Rt	Monzon, M. et al., "Synergy of different antibiotic combinations in biofilms of Staphylococcus epidermidis," The Journal of Antimicrobial Chemotherapy, 48:793-801 (2001).
· Rt	Morck, D.W. et al., "Microbial biofilms: prevention, control, and removal," In <u>Disinfection, Sterilization and</u> Preservation, Block S.S. (ed), 673-681 (2001).
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fr	Nichols et al., "The penetration of antibiotics into aggregates of mucoid and non-mucoid Pseudomonas aeruginosa," J. Gen. Microbiol., 135:1291-1303 (1989)
er	Nickel, C.J. et al., "Electron microscopic study of an infected foley catheter," The Canadian Journal of Surgery, 28: 50-52 (1985).
RE	Nickel, C.J. et al., "Bacterial biofilm in persistent penile prosthesis-associated infection," Journal of Urology, 135:586-588 (1986).
RZ	Ollos, P.J. et al. "Bench scale investigations of bacterial regrowth in drinking water distribution systems," Water Science & Technology, 38:275-282 (1998).
Rt	O'Sullivan et al., "Traits of fluorescent Pseudomonas spp. Involved in suppression of plant root pathogens," Microbiol. Rev. 56:662-676 (1992)
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12	O'Toble et al., "Flagellar and twitching motility are necessary for Pseudomonas aeruginosa biolilin
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PZ	Pesci et al., "Regulation of las and rhl quorum-sensing in <i>Pseudomonas aeruginosa</i> ," J. Bacteriol., 179:3127-3132 (1997)
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RX	Rahme et al., "Common virulence factors for bacterial pathogenicity in plants and animals," Science. 268:1899-1902 (1995)
· RZ	Rahme et al., "Use of model plant hosts to identify <i>Pseudomonas aeruginosa</i> virulence factors," Proc. Natl. Acad. Sci. USA, 94:13245-13250 (1997)
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pt	Reimmann et al., "The global activator GacA of <i>Pseudomonas aeruginosa</i> PAO positively controls the production of the autoinducer N-butyryl-homoserine lactone and the formation of the virulence factors pyocyanin, cyanide and lipase," Mol. Microbiol., 24:309-319 (1997)
比	Rich et al., "Genetic eveidence that the gacA gene encodes the cognate response regulator for the lemA sensor in <i>Pseudomonas syringae</i> ," J. Bacteriol., 176:7468-7475 (1994)
ft	Riosen, P.A. et al., "Identification of the DNA-binding sites for two response regulators involved in control of bacteriocin synthesis in Lactobacillus plantarum C11," Molecular and General Genetics, 259:224-232 (1998).
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BZ	Rumbaugh et al., "Contribution of quorum sensing to the virulence of <i>Pseudomonas aeruginosa</i> in burn wound infections," Infect. Immun. 67:5854-5862 (1999)
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ρł	Sambrook, J. et al., "Molecular Cloning: A Laboratory Manual," Cold Spring Harbor Laboratory Press (1989).
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RZ	Schweizer, H., "Small broad-host-range gentamycin resistance gene cassettes for site-specific insertion and deletion mutagenesis," BioTechniques, 15(5):831-832 (1993).
Examiner	Date

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PZ	Schwyn, B. et al., "Universal chemical assay for the detection and determination of siderophores," Anal. Biochem, 160:47-56 (1987)							
Rt								
RZ								
RZ	Seveno, N.A. et al., "Growth of Pseudomonas aereofasciens PGS12 and the dynamics of HHL and phnezine production in liquid culture, on nutrient agar and on plant roots," Microb. Ecol., 41:314-324 (2							
RZ	Simon, R. et al., "A broad host range mobilization system for in vivo genetic engineering: transposon mutagenesis in gram negative bacteria," Biotechnology, 1:784-791 (1983).							
RZ	Singh et al., "Quorum-sensing signals indicate that cystic fibrosis lungs are infected with bacterial biofilms," Nature, 407:762-764 (2000)							
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

# **'INFORMATION DISCLOSURE'** STATEMENT BY APPLICANT

of

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Sheet

Complete if Known **Application Number** 10/828,557 Filing Date April 21, 2004 **First Named Inventor** Douglas G. Storey et al. ROBERT A ZEMAN **Examiner Name Attorney Docket Number** 028722-381

NON-PATENT LITERATURE DOCUMENTS				
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
RE	Whistler et al., "The two component regulators GacS and GacA influence accumulation of stationary phase sigma factor σS and the stress reponse in Pseudomonas fluorescens Pf-5," J. Bacteriol., 180:6635-6641 (1998)			
RZ	Whiteley, M. et al., "Gene expression in Pseudomonas aeruginosa biofilms," Nature, 413:860-864 (2001).			
RE	Willis, D.K. et al., "Isolation and characterization of a Pseudomonas syringae pv. Syringae mutant deficient in lesion formation on bean," Molecular Plant-Mibrobe Interations, 3:149-156 (1990).			
RZ	Wohleben, W. et al., "On the evolution of Tn21 multiresistance transposons: Sequence analysis of the gene (aaaC1) for gentamicin acetyltransferase-3-I(AAC(3)-I), another member of the Tn21-based expression cassette," Molecular and General Genetics, 217:202-208 (1989).			
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RE	Yanke, S. et al., "Serum immune response to Girardia duodenalis in experimentally infected lambs," Veterinary Parasitology, 75:9-19 (1998).			
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